

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Danishefsky *et al.* Examiner: Not yet assigned
Serial No.: Not yet assigned Art Unit: Not yet assigned
Filed: June 19, 2003
For: TRIMERIC ANTIGENIC O-LINKED GLYCOPEPTIDE CONJUGATES,
METHODS OF PREPARATION AND USES THEREOF

Mail Stop Patent Application
Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

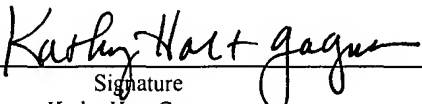
The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
☐ A *supplemental* Information Disclosure Statement.

Certificate of Mailing

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I hereby certify that this correspondence is being deposited with the United States Postal Service as "*Express Mail Post Office to Address*" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



Signature
Kathy Hart Gagnon

Typed Name

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:

☒ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

☐ Before the mailing of a first Office action on the merits; or

☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk, a † or a †† is included;
- ☒ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/276,595	March 25, 1999	Pending

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

[] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

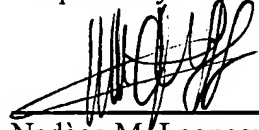
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



Nadège M. Lagneau, Ph.D.
Reg. No. 51,908

Dated: June 19, 2003

PATENT GROUP
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
Tel: (617) 248-5000
Fax: (617) 248-4000

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:
June 19, 2003

Group: Not yet
assigned

U. S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,053,489	Kufe <i>et al.</i>	10/1/91	530	350
	* 5,212,298	Rademacher <i>et al.</i>	5/18/93	536	55.2
	* 5,229,289	Kjeldsen <i>et al.</i>	7/20/93	435	240.27
	* 5,280,113	Rademacher <i>et al.</i>	1/18/94	536	55.2
	5,376,531	Anderson <i>et al.</i>	12/27/94	435	240.24
	* 5,421,733	Nudelman <i>et al.</i>	6/6/95	435	105
	5,491,088	Hellerstrom <i>et al.</i>	2/13/96	435	240.24
	5,625,030	Williams <i>et al.</i>	4/29/97	528	361
	* 5,660,834	Kjeldsen <i>et al.</i>	8/26/97	424	277.1
	5,679,769	Danishefsky	10/21/97	530	322
	* 5,683,674	Taylor-Papadimitriou <i>et al.</i>	11/4/97	424	1.49
	* 5,747,048	Kjeldsen <i>et al.</i>	5/5/98	424	277.1
	5,798,090	Longnecker <i>et al.</i>	8/25/98	424	279.1
	5,807,559	Jondal <i>et al.</i>	9/15/98	424	278.1
	* 5,858,994	Kretzschmar <i>et al.</i>	01/12/99	514	62
	5,871,990	Clausen <i>et al.</i>	2/16/99	435	193

Form PTO-1449
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket:
2003080-0127
(SK-816-CON)

In re Application No.
Not yet assigned

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:
June 19, 2003

Group: Not yet
assigned

	6,013,779	Wong <i>et al.</i>	1/11/00	536	18.6
	* 6,222,020	Taylor-Papadimitriou <i>et al.</i>	4/24/01	530	395
	6,238,668	Danishefsky <i>et al.</i>	5/29/01	424	184.1

U. S. PATENT APPLICATIONS

	Document No.	Applicant	Filing Date		
	†† USSN 08/457,485	Taylor-Papadimitriou <i>et al.</i>	6/1/95		
	† USSN 09/083,776	Danishefsky <i>et al.</i>	3/25/98		
	† USSN 10/205,021	Danishefsky <i>et al.</i>	7/25/02		

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Publication Date	Translation	
				Yes	No
	EP 341252 ✓	EP	11/19/97		
	JP 8-319300 ✓	JP	12/3/96		X
	WO 96/34005 ✓	PCT	10/31/96		
	WO 96/40198 ✓	PCT	12/19/96		
	WO 98/30190 ✓	PCT	7/16/98		
	* WO 98/46246	PCT	10/22/98		
	WO 99/48515 ✓	PCT	9/30/99		
	WO 01/14395 ✓	PCT	03/01/01		

Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003080-0127 (SK-816-CON)	In re Application No. Not yet assigned
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				Applicant: Danishefsky <i>et al.</i>	
				Filing Date: June 19, 2003	
				Group: Not yet assigned	
Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	Allen, <i>et al.</i> , "A Second Generation Synthesis of the MBrl (Globo-H) Breast Tumor Antigen: New Application of the N-Pentenyl Glycoside Method for Achieving Complex Carbohydrate Protein Linkages", <i>Chem. Eur. J.</i> , 6 (8): 1366-1375, 2000.				
	Balcom, B.J. and Petersen, N.O., "Synthesis and Surfactant Behavior of an Unusual Cyclic Triester Based on a <i>cis</i> , <i>cis</i> -1, 3, 5-Cyclohexanetriol Headgroup," <i>Langmuir</i> , 7 :2425-2427, 1991.				
	Bayle, <i>et al.</i> , "O-(3-Butenyl) A Stable Blocking Group Removable by Ozonolysis", <i>Carbohydrate Research</i> , 232 : 375-380, 1992.				
	* Bencomo <i>et al.</i> , "Synthesis of glycopeptides having clusters of O-glycosylic disaccharide chains. . .," <i>Carbohydrate Research</i> , 116 , C9-C12, 1983.				
	Bilodeau M.T., "Total Synthesis of a Human Breast Tumro Associated Antigen", <i>J. Am. Chem. Soc.</i> , 117 :7840-7841, 1995.				
	Boehm T. <i>et al.</i> , "Development of a Novel Silyl Ether Linker for Solid-Phase Organic Synthesis" <i>J. Org. Chem.</i> , 61 :6498-6499, 1996.				
	Boon, T., "Toward a Genetic Analysis of Tumor Rejection Antigens," <i>Adv. Can. Res.</i> , 58 :177-211, 1992.				
	Broddefalk, <i>et al.</i> , "Preparation of a Glycopeptide Analogue of Type II Collagen - Use of Acid Labile Protective Groups for Carbohydrate Moieties in Solid Phase Synthesis of O-Linked Glycopeptides", <i>Tetrahedron Letters, NL, Elsevier Science</i> , 37 (17): 3011-3014, 1996.				
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	Chan <i>et al.</i> , "Polymer-anchored Organosilyl Protecting Group in Organic Synthesis," <i>J. Chem. Soc., Chem. Commun.</i> , 909-911, 1985.				
	Collins and Ferrier "Monosaccharides: Their Chemistry and Their Roles in Natural Products, Publ. by John Wiley & Sons, Ltd., page 4, 1995.				
	Commissions on Nomenclature of Organic Chemistry and Physical Organic Chemistry, IUPAC, <i>Pure and Applied Chemistry</i> , 67 , 1325 and 1334, 1995.				
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	Danishefsky <i>et al.</i> "From the Laboratory to the Clinic: A Retrospective on Fully Synthetic Carbohydrate-Based Anticancer Vaccines" <i>Angew. Chem. Int. Ed. Engl.</i> , 39 :836-863, 2000.				
	Dermer, G.B., "Another Anniversary for the War on Cancer," <i>Bio/Technology</i> , 12 , 320, 1994.				
	Deshpande <i>et al.</i> , "Strategy in Oligosaccharide Synthesis: An Application to a Concise Total Synthesis of the KH-1 (Adenocarcinoma) Antigen," <i>J. Am. Chem. Soc.</i> , 120 , 1600-1614, 1998.				

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		<table border="1"> <tr> <td data-bbox="73 430 300 493"></td> <td data-bbox="316 430 1534 493"> * Elofsson and Kihlberg, "Synthesis of Tn and Sialyl Tn Building Blocks for Solid Phase Glycopeptide Synthesis," <i>Tetrahedron Letters</i>, 36, 7499-7502, 1995 </td> </tr> <tr> <td data-bbox="73 504 300 567"></td> <td data-bbox="316 504 1534 567"> * Elofsson <i>et al.</i>, "Preparation of Tn and Sialyl Tn Building Blocks. . .," <i>Tetrahedron</i>, 53, 369-390, 1997. </td> </tr> <tr> <td data-bbox="73 577 300 619"></td> <td data-bbox="316 577 1534 619"> Ezzell, "Cancer "Vaccines": An Idea Whose Time Has Come?" J. NIH Res, 7, 46-49, 1995. </td> </tr> <tr> <td data-bbox="73 630 300 703"></td> <td data-bbox="316 630 1534 703"> Finn <i>et al.</i>, "MUC-1 Epithelial Tumor Mucin-based Immunity and Cancer Vaccines" <i>Immunol. Rev.</i>, 145, 61-89, 1995. </td> </tr> <tr> <td data-bbox="73 714 300 777"></td> <td data-bbox="316 714 1534 777"> Fraser-Reid, <i>et al.</i>, "N-Pentenyl Glycosides in Organic Chemistry: A Contemporary Example of Serendipity", <i>Synlett</i>, 927-942, 1992. </td> </tr> <tr> <td data-bbox="73 787 300 850"></td> <td data-bbox="316 787 1534 850"> Freshney, R.I., "Culture of Animal Cells, A Manual of Basic Techniques, Alan R. Liss, Inc., New York, p. 3-4, 1983. </td> </tr> <tr> <td data-bbox="73 861 300 924"></td> <td data-bbox="316 861 1534 924"> * Fung <i>et al.</i>, "Active Specific Immunotherapy of Murine Mammary. . .," <i>Cancer Research</i>, 50, 4308-4314, 1990. </td> </tr> <tr> <td data-bbox="73 934 300 997"></td> <td data-bbox="316 934 1534 997"> Garg <i>et al.</i>, "Developments in the Synthesis of Glycopeptides Containing Glycosyl L-Asparagine, L-Serine, and L-Threonine" <i>Adv. Carb. Chem. 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Chem. Int. Ed. Engl.</i>, 25, 360-362, 1986. </td> </tr> <tr> <td data-bbox="73 1795 300 1869"></td> <td data-bbox="316 1795 1534 1869"> * Kunz <i>et al.</i>, "Construction of Disaccharide N-Glycopeptides – Synthesis of the Linkage Region of the Transmembrane-Neuraminidase of an Influenza Virus," <i>Angew. Chem. Int. Ed.</i> </td> </tr> </table>			* Elofsson and Kihlberg, "Synthesis of Tn and Sialyl Tn Building Blocks for Solid Phase Glycopeptide Synthesis," <i>Tetrahedron Letters</i> , 36, 7499-7502, 1995		* Elofsson <i>et al.</i> , "Preparation of Tn and Sialyl Tn Building Blocks. . .," <i>Tetrahedron</i> , 53, 369-390, 1997.		Ezzell, "Cancer "Vaccines": An Idea Whose Time Has Come?" J. NIH Res, 7, 46-49, 1995.		Finn <i>et al.</i> , "MUC-1 Epithelial Tumor Mucin-based Immunity and Cancer Vaccines" <i>Immunol. Rev.</i> , 145, 61-89, 1995.		Fraser-Reid, <i>et al.</i> , "N-Pentenyl Glycosides in Organic Chemistry: A Contemporary Example of Serendipity", <i>Synlett</i> , 927-942, 1992.		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INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:
June 19, 2003

Group: Not yet
assigned

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Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003080-0127 (SK-816-CON)	In re Application No. Not yet assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				Applicant: Danishefsky <i>et al.</i>	
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EXAMINER			DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

* denotes references cited in IDS and supplemental IDS submitted for parent application USSN 09/276,595, filed March 25, 1999.

† denotes references cumulative with WO 98/46246; copies of references are not included.

†† Cited document is not at present available to the undersigned, or is available in the file of a prior related application relied upon for an earlier filing date under 35 U.S.C. § 120.